K100714

APR - 1 2011

21. 510(k) SUMMARY - SAFETY AND EFFECTIVENESS

Applicant / Contact:

Cedars-Sinai Medical Center
Department of Medicine
Artificial Intelligence in Medicine Program
8700 Beverly Blvd.
Los Angeles, CA 90048
Tel: 310-423-4663
Fax: 310-423-0173

Preparer / Consultant:

Erik Rodriguez
Global Regulatory Solutions
2143 Country Place
Escondido, CA 92026
(858) 722-3353
erodriguez@grsolutions.us

A. Submitted By:

Cedars-Sinai Medical Center
Department of Medicine
Artificial Intelligence in Medicine Program
8700 Beverly Blvd.
Los Angeles, CA 90048
Tel: 310-423-4663
Fax: 310-423-0173

Contact Person:
Mr. Geoff Pollard, Project Manager
(At Address Above)

B. Device Trade Name:	CSMC Cardiac Suite
Common Name:	Nuclear Medicine Software Application
Classification Name:	Emission Computed Tomography System
Device Class:	21 CFR 892.1200, Class II
Product Code:	90 KPS

C. Date prepared: March 3, 2010

D. Predicate Device(s): AutoQUANT® Plus and Cedars-Sinai BPGS and MoCo Software Programs

Manufacturer	Product Name	510(k) No.
ADAC Laboratories	AutoQUANT® Plus	K060020
GE/SMV America	Cedars-Sinai BPGS/MoCo Software Programs	K010509

PRODUCT NAME	510(k) NUMBER	CLEARANCE DATE	MANUFACTURER
AutoQUANT® Plus	K060020	January 20, 2006	ADAC Laboratories 540 Alder Dr. Milpitas, CA 95035
Cedars-Sinai BPGS and MoCo Software Programs	K010509	April 27, 2001	GE/SMV America 8380 Darrow Road Twinsburg, OH 44087

E. Intended Use:
The CSMC Cardiac Suite is intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. CSMC Cardiac Suite may be used in multiple settings including the hospital, clinic, doctors office, or remotely. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

F. Device Description:
The Cedars-Sinai Cardiac Suite is a stand-alone software solution for Cardiac SPECT and PET imaging processing and review. Cedars-Sinai Cardiac Suite minimum system requirements include a computer with at least 1GB RAM, 50MB hard disk space for software installation, a display resolution at least 1024x768 with 16-bit color, a network adapter, a mouse (or other pointer device; trackpad, trackball, etc.) and one of the following operating systems: Windows XP Professional, Windows Vista Professional, Windows 7 Professional. The Cedars-Sinai Cardiac Suite operates on camera independent reconstructed SPECT and/or PET image files.

CSMC Cardiac Suite will be marketed as a comprehensive application suite that includes QGS (Quantitative Gated SPECT), QPS (Quantitative Perfusion SPECT) and CSImport applications. This allows automatic processing and

review of quantitative and qualitative information generated by nuclear medicine studies. Purchasable Options consist of Quantitative Blood Pool SPECT (QBS), QARG (for reporting purposes), Fusion (SPECT/CT/CTA and/or PET/CT/CTA), Motion Correction (MOCO) and QPET. QPET also includes viability quantification and two additional databases (rubidium and ammonia) for processing PET studies.

G. Technological Comparison:

CSMC CARDIAC SUITE has similar indications for use and overall function and performs in a similar manner with respect to data display and analysis to both predicates listed herein. Cardiac Suite is also equivalent to AutoQUANT Plus, QPS, QGS, QBS, QARG applications (K060020) and MoCo (K010509).

H. Testing:

Testing was conducted to demonstrate that each software application functioned as per its specifications. The summary of all verification tests are listed in the table below. Unresolved Anomalies are referenced herein:

Summary of Test Results

Test Description	Date	Build	Pass	Fail
Known Issues	2010-03-01	N/A	N/A	10
QPS Verification	2009-12-24	13291	1211	0
QGS Verification	2009-12-24	13250	1211	0
QBS Verification	2009-12-24	13250	632	0
QARG Verification	2009-12-21	13250	1161	0
CSImport Verification	2009-12-23	13291	111	2
MOCO Verification	2009-12-21	13250	23	0
Installation Verification	2009-12-21	13291	82	0
Regression	2010-03-01	13397	912	0
Regression	2010-02-28	13395	912	0
Regression	2010-02-27	13395	912	0
Regression	2010-02-26	13395	912	0
Regression	2010-02-25	13394	912	0

** Regression tests are run nightly; only the last 5 regression tests are listed*

Performance Testing

CSMC Cardiac Suite utilizes several algorithms requiring performance testing. With the exception of two new algorithms ("Quality Score" and "RV algorithm") all algorithms operate identically (i.e. produce the same results) as with previous

versions of the software (referenced in predicate devices). In order to ensure the algorithms operate identically to predicate devices a set of 16 studies' algorithm results are compared to those of the predicate device. These test results are included in our regression tests.

Substantially Equivalent/Conclusion

CSMC CARDIAC SUITE is is substantially equivalent to AutoQUANT Plus, QPS, QGS, QBS, QARG applications (K060020), MoCo (K010509) previously cleared by FDA. The CSMC Cardiac Suite has similar indications for use and overall function and performs in a similar manner with respect to data display and analysis as the predicate devices AutoQUANT Plus. This updated version of QPS (Quantitative Perfusion SPECT) and QGS (Quantitative Gated SPECT) includes an automatic registration algorithm between SPECT/PET and CT/CTA datasets, an improved contouring algorithm based on a quality score and RV (right ventricle) extraction and analysis. Therefore, this premarket notification has demonstrated substantial equivalence as defined and understood in the Federal Food, Drug, & Cosmetic Act and its amendments.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Geoff Pollard, Project Manager
Cedars-Sinai Medical Center
Department of Medicine, Artificial Intelligence in Medicine Program
8700 Beverly Blvd.
LOS ANGELES CA 90048

APR - 1 2011

Re: K100714
Trade/Device Name: Cedars-Sinai Cardiac Suite
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: October 29, 2010
Received: October 29, 2010

Dear Mr. Pollard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100714

Device Name: Cedars-Sinai Cardiac Suite

Indications for Use:

The Cedars-Sinai Cardiac Suite of applications is intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. Cedars-Sinai Cardiac Suite may be used in multiple settings including the hospital, clinic, doctors office, or remotely. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

Prescription Use ✓ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Mary S Patel

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100714